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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,306	10/25/2001	Murali Nayudu	13377-002001	8939

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Fish & Richardson
225 Franklin Street
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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,306	Applicant(s) NAYUDU ET AL.	
	Examiner Vera Afremova	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 28-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 24-27 and 73-102 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/07/02; 9/23/02; 1/21/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group III (original claims 24-27), drawn to an isolated biocontrol agent in a form of bacterial cell(s) related to the strain AN5 rif (AGAL accession no. 00/09624), in paper(s) filed 3/08/2004 is acknowledged.

Claims 1-23 and 28-72 have withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper(s) filed 3/08/2004.

Claims 24-27 and new claims 73-102 are under examination in the instant office action.

Specification

Applicants are reminded herein that the current address of the depository collection that is Australian Government Analytical Laboratories (AGAL) should be updated, if changes occurred. See specification page 27.

Claim Rejections - 35 USC § 112

Indefinite

Claims 24-27 and 73-102 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite as related to the phrase "biocontrol properties" of *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624) because it is uncertain what are the claimed properties in the lack of definitions and/or protocol of evaluation of a degree of biocontrol

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effect(s). It is uncertain whether all or some properties of the claimed strain are intended. What is the claimed bacterial entity as related to the specific strain AN5 rif?

Claims 25-27 are rendered indefinite by the phrase "derivatives" because it is uncertain what strains or cells would be "derivatives" as intended, what characteristics the "derivatives" would have and/or what would be protocols of their evaluation in order to compare AN5 or to AN5 rif to establish the "enhanced" capacity as intended.

Claims 75, 89 and 99 are rendered indefinite by the phrase "PQQ-dependent manner" because it is uncertain what characteristics and/or properties are claimed.

Deposit

Claims 24-27 and 73-102 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism that is *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624). Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The specification discloses that the presently claimed *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624) is a spontaneous mutant and, thus, the method of making this strain is unpredictable and not easily repeatable. The specification does not appear to disclose "derivatives" further obtained from the strain AN5 rif. If the microorganism(s) is not obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the

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microorganism. But it is not clear from the specification or record that the microorganism(s) is readily available to the public.

The rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because the Australian Government Analytical Laboratories (AGAL) has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions with respect to the claimed strain AN5 rif (AGAL accession no. 00/09624) will be irrevocably removed upon issuance of the patent will overcome this rejection as applied to the claimed strain AN5 rif (AGAL accession no. 00/09624).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27, 73-80, 82-84, 86-94 and 96-102 are rejected under 35 U.S.C. 102(b) as being anticipated by Nayudu et al. {IDS filed 1/07/2002, reference AP}.

Claims are directed to an isolated biocontrol agent comprising bacterial cell(s) that belong to the genus of *Pseudomonas*, that are not the cells of the strain AN5, that produce sugar acid when cultured on aldose sugar and that are capable to colonize sites of fungal plant pathogens. The claimed cell(s) has the biocontrol properties of the strain AN5 rif that is ability to grow on an aldose sugar and to produce the sugar acid and the anti-fungal plant pathogen effects. Some claims are further drawn to the agent ability to convert glucose to glucuronic acid and to the agent anti-fungal effects towards *Gaeumannomyces graminis* (Gr or take-all fungus). Some claims are further drawn to methods for treating a fungal plant infection and for protecting a post-harvest plant product by applying the agent to the plant or to the plant post-harvest product.

The reference by Nayudu et al. discloses several mutants that derived from the parent strain AN5 and, thus, are not the cells of the strain AN5 within the meaning of the claims (page 122, col. 2, par. 1). These isolated mutants/derivatives are capable to utilize sugar such as glucose and, thus, to produce acid such as gluconic acid at least to the some degree as the parent strain AN5. These isolated mutants/derivatives are capable to produce biocontrol effects against fungal plant pathogens including fungus *Gaeumannomyces graminis* (Gr or take-all fungus) at least to the some degree as the parent strain. Therefore, the mutants/derivatives disclosed by the cited reference are reasonably expected to have identical properties as the "biocontrol properties" of the claimed strain AN5 rif because the presently claimed strain is also the mutant/derivative of the same parent strain AN5 as the disclosed mutants/derivatives. Thus, the cited reference anticipates the presently claimed composition comprising bacterial cells as claimed.

With respect to claims 75, 89 and 99 it is noted that although the cited reference is silent with regard to the "PQQ-dependent manner" of converting aldose sugar to acid, the disclosed mutants/derivatives are reasonably expected to possess this ability at least to some degree because they are derivatives of the parent strain AN5 that is disclosed as having the ability or genes as related to the claimed properties of the "PQQ-dependent manner" (see specification page 39, line 25). Thus, the mutants/derivatives of the cited reference, that utilize glucose and produce anti-fungal effects, inherently contain at least some of the genes related to the "PQQ-dependent manner" within the meaning of the claims.

The cited reference also teaches method of treating fungal take-all *Gaeumannomyces graminis* Gr plant pathogen infection on the agar plates and in the plant-pot assays by using the isolated mutants/derivatives (page 12, col. 1, par. 3). The cited reference also teaches method of protecting post-harvest plant product such as plant seeds wherein the method comprises one active step of seed treatment with the isolated mutants/derivatives. Thus, the cited reference anticipates the presently claimed methods of using the claimed composition comprising bacterial cells as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-27 and 73-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nayudu et al. {IDS filed 1/07/2002, reference AP} taken with Dahiya et al. {Bot. Bull.

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Academia Sinica (1988), 29: 135-142}, Scnider et al. {IDS filed 1/07/2002, reference AQ} and US 4,456,684.

Claims 24-27, 73-80, 82-84, 86-94 and 96-102 as explained above. Some claims are further drawn to the agent ability to produce anti-fungal effects towards *Botrytis fabae*.

The reference by Nayudu et al. teaches bacterial agent or cells that clearly effective against plant pathogens including fungus *Gaeumannomyces graminis*. But it is missing disclosure with regard the anti-fungal effects towards *Botrytis fabae*.

However, the reference by Dahiya et al. demonstrates that bacterial cells belonging to *Pseudomonas* as the cells of the reference by Nayudu et al. are capable to produce pyrrolnitrin and phenazine antibiotics that are active against fungal plant pathogens belonging to *Gaeumannomyces* and to *Botrytis* (see abstract).

Further, the reference by Scnider et al. is relied upon to demonstrate that bacterial cells belonging to *Pseudomonas* as the cells of the references by Nayudu et al. and by Dahiya et al. produce various antibiotics active towards various plant pathogens, are capable to utilize glucose and possess genes related to the PQQ biosynthesis (page 3856, col. 1 and 2).

Furthermore, the cited US 4,456,684 is relied herein upon to demonstrate the anti-fungal protective amounts of *Pseudomonas* bacterial cells that are effective in the methods for treating fungal infections of plants and for protecting post-harvest plant products or seeds (col. 9, lines 46-50; col. 6, lines 59-61). Although the bacterial strains disclosed by US 4,456,684 are not derived from the strain AN5 but they are isolated from soil, they are capable to utilize an aldose sugar glucose (col. 10, line 41) and to produce anti-fungal effects, and, thus, they are

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substantially similar, is not identical, to the presently claimed “derivatives” within the meaning of the claims.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain a biocontrol agent composition with bacterial cells belonging to *Pseudomonas* as encompassed by the presently claimed invention with a reasonable expectation of success in the possession of the agent intended for treating fungal plant pathogen infections including that belonging to *Gaeumannomyces* and to *Botrytis* because the bacterial cells belonging the *Pseudomonas* have been taught to produce antifungal effects towards the same group of plant pathogens as the presently claimed bacterial agent. The claimed characteristics as related to the PQQ manner or PQQ biosynthetic pathways have been known within the group of bacteria belonging to *Pseudomonas* that produce anti-fungal effects. The amounts of *Pseudomonas* bacterial cells that are effective for treating fungal plant pathogens have been taught in the prior art. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

May 27, 2004



VERA AFREMOVA

PATENT EXAMINER